

Remarks

Claims 37-67 are pending in the application. Claims 37-64 have been withdrawn.

Claim 67 is newly added. Please reconsider this application in view of the above amendments and the following remarks. The numbered paragraphs below correspond to the numbered paragraphs in the Office Action.

2. Applicants acknowledge constructive election and withdrawal of Claims 37 and 41.

3. Applicants acknowledge Claims 37 and 41 have been withdrawn for the reasons set forth in paragraph 2 of the Office Action, and newly added claims 65 and 66 were added by the Examiner to the original rejection under 35 U.S.C. 102.

4/5. Claims 65 and 66 were rejected under 35 U.S.C. 102(b) as being anticipated by Ragheb et al. ("Ragheb"), USPN 5,824,049.

Claim 65 as amended recites, "**reservoir layer comprising a drug dispersed in the reservoir layer.**"

The Examiner is unclear how the drug and polymer interact within the reservoir layer. In response, the Applicants respectfully direct attention to page 20, lines 18-23, stating,

"Sufficient amounts of an active ingredient are dispersed in the blended composition of the polymer and solvent. The active ingredient should be in true solution or saturation in the blended composition. If the active ingredient is not completely soluble in the composition, operations including mixing, stirring, and/or agitation can be employed to effect homogeneity of the residues."

Thus, the Specification clearly sets out how the drug and polymer interact within the reservoir layer -- the drug is dispersed in the reservoir layer.

Ragheb describes a coating configuration that has a layer on the surface of the device, a layer of a pure drug or combination of drugs, and a porous polymer layer on top of the pure drug layer for the controlled release of the drug. The porous polymer layer is described as “a network resembling a fibrous mesh with relatively large pores” (Col. 10, lines 52-54). Ragheb teaches that:

“[c]areful and precise control over the deposition of the parylene or parylene derivative therefore permits close control over the release rate of material from at least one layer 18 of bioactive material. It is for this reason that the **bioactive material lies under the at least one porous layer 20, rather than being dispersed within or throughout it**” (Col. 10, lines 57-64).

In other words, Ragheb indisputably denounces a **reservoir layer comprising a drug dispersed in the reservoir layer** as in amended Claim 65 of the present invention. Therefore, amended Claim 65 is patentably allowable over Ragheb.

With respect to Claim 66 of the invention, Claim 66 includes unsaturated polymers such as polyester diacrylates, polycaprolactone diacrylates, polytetramethylene glycol diacrylates, and polyacrylates with at least two acrylate groups, polyacrylated polyurethanes, tiracrylates or any combination thereof.

The Examiner asserts that Ragheb discloses polymers including photopolymerizable polyethylenically unsaturated acrylic esters containing two or more acrylate groups per molecule such as trimethylpropane triacrylate (Column 11, lines 21-39). While the Office Action agreed with the Applicants’ assertion that for the particular

monomer trimethylopropane triacrylate, when combined with another monomer, acrylates would polymerize to leave a saturated backbone (Office Action, page 4), the Office Action states that monomers of photopolymerizable polyethylenically unsaturated acrylic esters containing two or more acrylate groups per molecule teach the present invention. Applicants respectfully submit that this is erroneous. The other examples of Column 11 in Ragheb, including photopolymerizable polyethylenically unsaturated acrylic esters containing two or more acrylate groups per molecule cited in the Office Action, also polymerize to leave a saturated backbone. It seems that polymerization of all acrylate-based monomers listed in Column 11 in Ragheb proceed via polymerization of the acrylate groups in the molecule, forming a saturated polymer with no acrylate groups. Ragheb therefore fails to teach unsaturated polymers as in Claim 66 of the invention.

Therefore, Claim 66 is patentably allowable over Ragheb.

6. Examiner acknowledges objection of Claim 41 has been withdrawn.
- 7-9. The Examiner agreed with the Applicants' assertion that for the particular monomer trimethylopropane triacrylate, when combined with another monomer, the acrylates would polymerize and leave a saturated backbone (Office Action, page 4). With respect to the other examples of Column 11 in Ragheb, just as monomers of trimethylopropane triacrylate, when combined with another monomer, the acrylate groups would polymerize to leave a saturated backbone (Office Action, page 4) -- in the same way, ethylene glycol diacrylate would polymerize to leave a saturated backbone. Further, polymerization of acrylate-based monomers listed in Column 11 in Ragheb proceed via polymerization of

the acrylate groups in the molecule, forming a saturated polymer with no acrylate groups, which teaches away from the **unsaturated polymers** recited in amended Claim 65 of the invention. With respect to Ragheb's disclosure of polyethylenically unsaturated acrylic esters containing two or more acrylates reading on polyester diacrylates, the same reasoning applies – basically, polyethelenically unsaturated acrylic esters containing two or more acrylates polymerize to leave a saturated backbone.

10-12. Claims 65 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Office Action states that the Markush group in Claim 65 contains species that overlap, for instance acrylates and high amine content polymers are included in unsaturated polymers. In response, Applicants respectfully submit that Claim 65 has been improperly rejected because the rejection is based on the sole reason that acrylates and high amine content polymers are included in unsaturated polymers:

“the double inclusion of an element by members of a Markush group is not, in itself, sufficient basis for objection to or rejection of claims. Rather, the facts in each case must be evaluated to determine whether or not the multiple inclusion of one or more elements in a claim renders that claim indefinite. **The mere fact that a compound may be embraced by more than one member of a Markush group recited in the claim does not necessarily render the scope of the claim unclear. For example, the Markush group, “selected from the group consisting of amino, halogen, nitro, chloro and alkyl” should be acceptable even though “halogen” is generic to “chloro.””** (MPEP 2173.05(h))

The mere fact that acrylates and high amine content polymers may be embraced by unsaturated polymers does not necessarily render the scope of the claim unclear. Please remove this rejection.

Further, the Office Action states that inorganic polymers as listed in Claim 65 include a number of possibilities. Applicants respectfully submit that claims to a genus have been clearly deemed allowable by the patent office. See, for example, MPEP 2173.05(h), stating,

"Genus, subgenus, and Markush-type claims, if properly supported by the disclosure, are all acceptable ways for applicants to claim their inventions. They provide different ways to present claims of different scope."

The standard is not "a number of possibilities," but rather whether the specification provides adequate support for a genus. Applicants respectfully submit that the specification provides ample support for the genus, "inorganic polymers", and, examples of species that fall within the genus are provided in the Specification, including silanes, titanates, zirconates (See Specification page 6, line 8, page 11, line 20 to page 12, line 2, and page 37, lines 3-5). Please remove this rejection.

13. Claim 66 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Office Action states that Claim 66 includes a Markush group comprising polyester diacrylates, polycaprolactone diacrylates, polytetramethylene glycol diacrylate, polyacrylates with at least two acrylate groups, polyacrylated polyurethanes, triacrylates, and any combination thereof. The Office Action states that the specific species "polyacrylates with at least two acrylate groups" is unclear. The Examiner is unclear whether Applicants are referring to diacrylates and/or

triacrylates, and that Markush already includes triacrylates, polyester diacrylates, and so on.

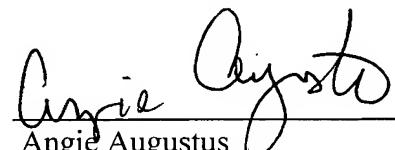
In response, Applicants assert that “polyacrylates with at least two acrylate groups” clearly include diacrylates, triacrylates, as well as polyacrylates with 4, 5, etc. acrylates, as suggested by the language “at least two acrylate groups.” Further, Applicants reassert that Claim 66 is definite for the reasons stated in paragraph 12 above. Specifically, the mere fact that diacrylates and triacrylates may be embraced by polyacrylates does not necessarily render the scope of the claim unclear. Please remove this rejection.

Withdrawal of the rejections and allowance of Claims 65-67 is respectfully requested. Since all claims are in a condition for allowance, please issue a Notice of Allowability. Should the Examiner have any questions regarding this response or comments that would move the case towards allowance, the Examiner is invited to call the undersigned attorney of record. The undersigned authorizes the examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

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Respectfully submitted,


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